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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of

Woodward et al

Serial No: 08/876,937

Filed: June 16, 1997

For: NON-ACIDIC CYCLOPENTANE HEPTANOIC ACID, 2-CYCLOALKYL OR ARYLALKYL DERIVATIVES AS THERAPEUTIC AGENTS

Group Art Unit: 1621

Examiner: P. O'Sullivan

Box Appeal Brief
Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

BRIEF ON APPEAL

Dear Sir:

This appeal is taken from the final rejection of all of the claims in an Examiner's action mailed March 2, 1999. Oral hearing is waived.

(1) REAL PARTY IN INTEREST

This patent application is assigned to Vision Pharmaceuticals L.P., having its principal place of business at 2525 Dupont Drive, Irvine, CA 92612.

(2) RELATED APPEALS AND INTERFERENCES

None.

(3) STATUS OF CLAIMS

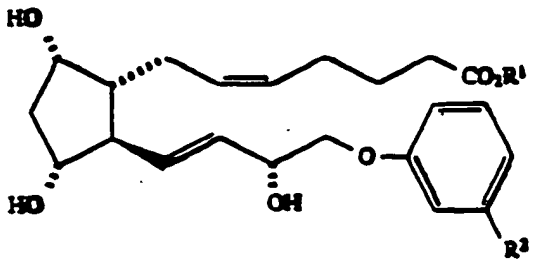
Claims	Status
26 through 45	Rejected under 35 USC § 102(e) as being anticipated by Bishop '383.
26, 28-34 and 36-45	Rejected under 35 USC § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(4) STATUS OF AMENDMENTS

A response was filed pointing out that the applicants were not required to file a declaration under 37 CFR § 1.608(b) as requested by the Examiner in the Final Rejection.

(5) SUMMARY OF THE INVENTION

The present invention provides a method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of a compound of formula:



wherein R^1 =hydrogen, a cationic salt moiety, a pharmaceutically acceptable amine moiety or C_1-C_{12} alkyl

cycloalkyl or aryl; and R^2 = Cl_1 or CF_3. (See claim 26.) Topical ophthalmic compositions useful in the method of the invention are also provided. (See claim 34.)

(6) ISSUES

Lack of Written Description

Whether Applicants have provided a written description of the invention in such a way as to reasonably convey to one skilled in the relevant art that at the time the relevant application was filed, they had possession of the claimed invention?

Anticipation

Whether all of the claims lack novelty over United States Patent Number 5,510,383 to Bishop et al (Bishop '383)?

(7) GROUPING OF CLAIMS

Group I, Written Description includes claims 26, 28 through 34 and 36 through 45.

As discussed below, it is believed that claims 42 through 45 are not subject to rejection under 35 USC § 112, first paragraph, even if claims 26, 28 through 34 and 36 through 41 are properly rejected.

Group II, Anticipation includes claims 26 through 45.

(8) ARGUMENT

WRITTEN DESCRIPTION

(i.) (A) The Rejection of the Claims of Group II Under 35 USC § 112, first Paragraph.

The Examiner rejected Claims 26, 28-34 and 36-45 under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner argues that group R^1 is broader than that shown in the specification in each case as originally filed. In particular, the Examiner argues that the Applicants' "pharmaceutically acceptable ester moiety" could contain an aryl group in the alcohol moiety which is not enabled in the specification. (It is not understood why the Examiner uses the term "not enabled", since it is believed that the rejection is for lack of a written description of the invention, not lack of enablement.) Furthermore, the Examiner argues that the other claims which depend from rejected generic claims, but do not further limit R1 to the scope originally in the specification, are rejected as well. (See the Final Rejection.) In particular, the Examiner states that the "Applicants' specification as filed discloses only R^1 is H, lower alkyl, or a cation, not the newly claimed groups." (See the first Office Action.) (It is noted that claims 27 and 35, wherein R^1 is H, CH_3, $CH(CH_3)_2$ or $C(CH_3)_3$ are not rejected under 35 USC § 112.)

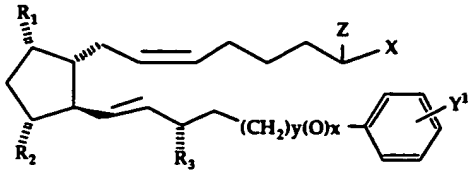
The applicants disagree with this rejection for the following reasons. The claims, as filed, are part of the specification. Therefore the claims themselves disclose the "newly added groups", i.e. the compounds wherein R^1 is other

than "H, lower alkyl or a cation". It is believed that, when the Examiner argues the group R^1 is broader than that shown in the specification as originally filed, he is referring to the parent of the present application i.e. U.S. Patent Application Serial No. 605,567 (the "'567 Application"), which parent application was filed on February 22, 1996. It is not necessary for the claims of the present invention to be supported in the '567 Application as originally filed, since the issue is whether the claims are supported in this application, however, there is such support. In fact, in the '567 Application the same claims as pending claims 26-45 were presented by amendment but were cancelled, without prejudice, to obtain the allowance of the claims, originally filed in the '567 Application which issued as U.S. Patent Number 5,688,819. (The '567 Application has an ultimate effective filing date through its grand parent application, i.e. U.S. Patent Application Serial No. 948,056, (the "Grandparent Application) of September 21, 1992. The Grandparent Application is discussed below under (8)(iii).)

This support in the '567 Application for element R^1 and the other limitations of the present claims may be taken from the '567 Application.

Original claim 4 of the '567 Application reads as follows:

4. The method of claim 3 wherein said compound is represented by the formula IV.



wherein Y^1 is Cl or trifluoromethyl.

According to claim 1 of the '567 Patent, Z may be O ||

X may be $-OR^4$, wherein R^4 may be hydrogen, or a lower alkyl radical; and R_1 and R_2 may be -OH. According to claim 2, y may be 0; X may be 1 and R_3 may be -OH. Also, according to claim 1 the compound of formula IV includes pharmaceutically acceptable salts.

Thus, reading claim 4 of the '567 Application, in view of claims 1 and 2, all the limitations of claim 1 of the Bishop Patent and claim 26 of the present patent are met in the '567 Application, except, as the Examiner argues, for R_1 is aryl. However, for the purpose of the present claims an alkyl ester is believed to be equivalent to the aryl ester of Bishop '383, since in the context of using the described compounds to treat glaucoma or ocular hypertension, it is not seen how an aryl ester differs from an alkyl ester.

Finally, it is not understood why the Examiner has rejected claims 42 through 45 under 35 USC § 112, first paragraph, since when R_1 is lower alkyl in claim 1 of Bishop '383 and present claim 26, as the Examiner agrees is supported by the present specification, the 1 position of the compound of the formula of said claim 1 of Bishop '383 and said claim 26 of the present application, is an ester moiety, as required by claims 42 through 45.

ANTICIPATION

(iii.) The Rejection of the Claims of Group I Under 35 USC § 102(e)

The Examiner rejected Claims 26-45 under 35 USC § 102(e) as being anticipated by Bishop '383 which discloses and claims the use of cloprostenol, fluprostenol, etc. to treat glaucoma and ocular hypertension. (See the Title of Bishop '383.) (The claims of the present application were

copied from Bishop for the purpose of providing an interference.) The Examiner has argued that (t)hese claims are not patentable to the applicant because they are rejected under 35 USC § 112, first paragraph and under 35 102(e) above. An interference cannot be initiated since a prerequisite for interference under 37 CFR § 1.606 is that claims be patentable to the applicant subject to a judgement in the interference." (Note, the Examiner has not rejected claims 27 and 35 under 35 USC § 112, first paragraph, therefore as to these claims, at least, the 35 USC § 102(e) rejection is incorrect. Moreover, even if the Examiner is right as to claims 26, 38 through 34 and 36 through 41, applicants believe, as argued above, that the Examiner is incorrect in his rejection of claims 42-45 under 35 USC § 112, first pargraph.)

Moreover, the applicants wish to point out that these claims 26 through 45 are arguably supported in the Grandparent Application which predates the filing date of Bishop '383 as follows:

It is clear that the applicants disclose in the Grandparent Application, the compound 16-m-chlorophenoxy $PGF_{2\alpha}$, i.e. cloprostenol which is the corresponding acid of the isopropyl ester designated as A in Table 1 of Bishop '383. (The acid, i.e. cloprostenol, is included in claim 1 of Bishop '383, i.e. where R^1 is hydrogen and R^2 is chlorine.) This compound is also shown at Table V of the Grandparent Application to be an effective IOP lowering agent both as an acid and as the 1-hydroxyl and 1-amido derivatives thereof. Note the methyl ester and the amido derivatives of 16-m-chloro phenoxy $PFG_{2\alpha}$, i.e. cloprostenol, are prepared in Examples 8 and 9 of the Grandparent Application while the 1-hydroxy derivative is prepared in Example 15 of the Grandparent Application.

The applicants also submitted a Declaration Under Rule 1.131 in the '567 Application which demonstrates that, prior to the filing date of Bishop '383, the applicants had reduced to practice the present invention as related to fluprostenol in the United States." (A copy of the Declaration under 37 CFR § 1.131 was filed in the present application for the Examiner's reference.) Fluprostenol is the corresponding acid of the isopropyl ester designated as B and is also included in claim 1 of Bishop '383, when R^1 is hydrogen and R^2 is CF_3.

Thus, as to the compounds upon which the invention of Bishop '383 is based, i.e. cloprostenol and floprostenol, applicants have either an earlier filing date or declaration showing a reduction to practice prior to the filing date of Bishop '383. The further disclosure of Bishop '383, that the acids cloprostenol and fluprostenol may be esterified or converted to a pharmaceutically acceptable salt for the purpose of treating glaucoma or ocular hypertension may be shown to be obvious in view of applicants showing of the same activity for said acids.

Furthermore, applicants believe that under 35 USC § 102(g) Bishop's claims may not be patentable since applicants believe that they may be able to show that the invention of Bishop "was made in this country by another", i.e. Woodward et al prior to the date of invention by Bishop. The Declaration under 35 USC § 131 was filed to show Woodward et al made the invention before Bishop et al's filing date. The Examiner is referred to Bates v. Coe 98 U.S. 31, 34 (1878) wherein it is stated that "the presumption in respect to the invention described in the patent in suit, if it is accompanied by the application for the same, is that it was made at the time the application was filed; and the complainant or plaintiff may, if he can, introduce proof to show that it was made at a much earlier date."

Thus, for two reasons, the Examiner is incorrect in his rejection under 35 USC § 102(e):

First, applicants are entitled to prove in an interference that they are the prior inventors and entitled to a patent on the invention defined in claims 26 through 45.

Second, the patentees, i.e. Bishop et al, may not be entitled to the patent under 35 USC § 102(g) since they were not the first to make the invention.

In summary, if the Examiner can take the position that in order to provoke an interference an applicant must show support for the claims according to 35 USC § 112, first paragraph, in an application that predates the filing date of a patent, then under U.S. Patent Law the first to file, not the first to invent, will obtain the patent. This is clearly not the law.

In view of the above, the Board is asked to reverse the Examiner's holding of all of the pending claims as unpatentable and direct the Examiner to pass the claims to issue.

Respectfully submitted,

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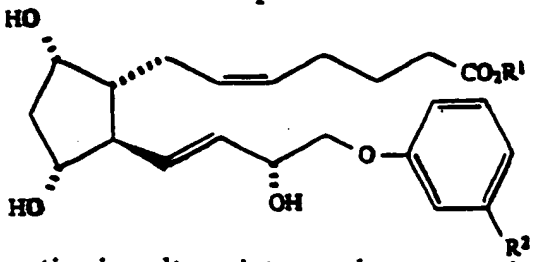
CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO: BOX APPEAL BRIEF COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231 ON 12/2/1999 Printed name of person making deposit: Bonnie Ferguson Signature of person making deposit: Bonnie Ferguson Date Signed: 12/2/1999

(7) APPENDIX

CLAIMS:

26. A method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of a compound of formula:



wherein R^1 =hydrogen, a cationic salt moiety, a pharmaceutically acceptable amine moiety or C_1-C_{12} alkyl cycloalkyl or aryl; and R^2 = Cl or CF_3.

27. The method of claim 26, wherein R^1 is selected from the group consisting of H, CH_3, $CH(CH_3)_2$ and $C(CH_3)_3$.

28. The method of claim 26, wherein R^1 is selected from the group consisting of Na^+ and $CH_3N^+(CH_2OH)_3$.

29. The method of claim 26, wherein R^2 is Cl.

30. The method of claim 27, wherein R^2 is CF_3.

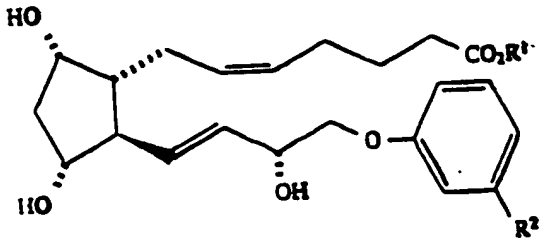
31. The method of claim 26, wherein between about 0.001 and about 1000 µg/eye of a compound of formula (I) is administered.

32. The method of claim 31, wherein between about 0.01 and about 100 µg/eye of a compound of formula (I) is administered.

33. The method of claim 31, wherein between about 0.05 and about 10 µg/eye of a compound of formula (I) is administered.

(7) APPENDIX (Cont.)

34. A topical ophthalmic composition for the treatment of glaucoma and ocular hypertension in primates, comprising a therapeutically effective amount of a compound of formula:



wherein: R^1 = hydrogen, a cationic salt moiety, a pharmaceutically acceptable amine moiety or C_1-C_{12} alkyl, cycloalkyl or aryl; and R^2 = Cl or CF_3.

35. The composition of claim 34, wherein R^1 is selected from the group consisting of H, CH_3, $CH(CH_3)_2$ and $C(CH_3)_3$.

36. The composition of claim 34, wherein R^1 is selected from the group consisting of Na^+ and $CH_3N^+(CH_2OH)_3$.

37. The composition of claim 34, wherein R^2 is Cl.

38. The composition of claim 34, wherein R^2 is CF_3.

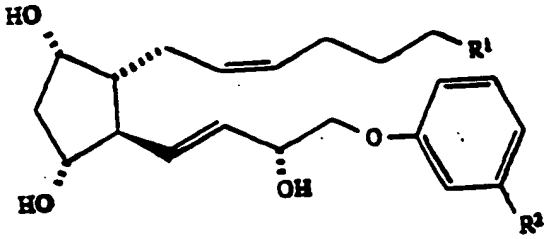
39. The composition of claim 34, wherein between about 0.001 and about 100 µg/eye of a compound of formula (I) is administered.

40. The composition of claim 39, wherein between about 0.01 and about µg/eye of a compound of formula (I) is administered.

(7) APPENDIX (Cont.)

41. The composition of claim 40, wherein between about 0.05 and about 10 μg/eye of a compound of formula (I) is administered.

42. A method of treating glaucoma and ocular hypertension, which comprises topically administering to the affected eye a therapeutically effective amount of a compound of formula:



wherein: R^1 = a pharmaceutically acceptable ester moiety; and R^2 = Cl or CF_3.

43. The method of claim 42, wherein R^2 is Cl.

44. The method of claim 42, wherein R^2 is CF_3.

45. The method of claim 42, wherein between about 0.001 and about 1000 μg/eye of a compound of formula (I) is administered.